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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,188

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Kota Ishibiki

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EXAMINER

CONLEY, SEAN EVERETT

ART UNIT

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1797

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DELIVERY MODE

12/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,188	Applicant(s) ISHIBIKI, KOTA	
	Examiner SEAN E. CONLEY	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/20/08, 8/13/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 6-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/20/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response filed August 13, 2008 has been received and considered.
Claims 1-23 are pending with claims 6-23 remaining withdrawn from consideration for being directed to a non-elected invention.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on June 20, 2008 has been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, both claims 3 and 4 recite a "material having softness" (see claim 3, line 3 and claim 4, lines 4-5). It is unclear whether or not the material is made of a soft material or if the material comprises something soft. Also, it is unclear what materials are encompassed by the term "softness". The term "softness" in claims 3 and 4 is a relative term which renders the claim indefinite. The term "softness" is not defined by the claim, the specification does not provide

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a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. (JP 2001070226 A – English language machine translation) in view of Palmers (U.S. Patent No. 6,251,345 B1).

Regarding claims 1 and 2, Ogawa et al. disclose a medical equipment autoclaving system comprising a communication vent (211) through which the inside of medical equipment (endoscope) and the outside thereof communicate with each other, a pressure adjusting means that includes a check valve (202) which opens, only when the pressure in the inside of the medical equipment which communicates with the outside thereof through the communication vent gets higher than the pressure in the outside thereof by a certain value or more (see paragraphs [0028], [0031], [0050]- [0059] of machine translation), and an autoclave that sterilizes the medical equipment, wherein the autoclave executes the following process (see paragraphs [0034]-[0059] of machine translation): a first depressurization process including a step of depressurizing the inside of a chamber included in the autoclave; an autoclaving process which succeeds the first depressurization process and in which the chamber is pressurized; and a

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second depressurization process succeeding the autoclaving process and including a step of depressurizing the chamber (see paragraph [0007]).

However, Ogawa et al. fails to specifically disclose an autoclave with a control unit capable of controlling the above mentioned vacuum and autoclaving processes.

Palmer's discloses an autoclave (9) for sterilizing medical instruments wherein the autoclave utilizes a control unit (central unit 26) having a (micro processor 25) to control the sterilization process. The control unit (central unit 26) controls the valves (23) which operate the inlet and outlet of different fluids, such as water, pressurized air, steam, cleaning agents, vacuum, and lubricants (see col. 3, lines 44-55; see col. 4, lines 27-33; see figures 1,3, 4; see col. 2, lines 31-31-37). Inside the central unit 26 is a micro processor 25 which controls the sterilization procedure in accordance with a chosen program and further, the micro processor 25 may be a full scale computer (see col. 3, lines 55-60; see col. 4, lines 27-33). As such, the control unit of Palmer's is capable of being configured to carry out depressurization (vacuum) processes and autoclaving (steam sterilization) processes in the configuration recited in applicant's claims.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Ogawa et al. and utilize the control unit exemplified by Palmer's, to control vacuum and autoclaving processes as claimed by the applicant, in order to provide an automated sterilization process with a controller that controls all phases required for having

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a medical instrument sterilized thus decreasing the chances for human error in the process.

Furthermore, it would have been obvious and well within the ordinary level of skill in the art to repeat the depressurization (vacuum drying process) a plurality of times with a lower pressure each time in order to achieve complete drying of the endoscope if drying does not occur after a single vacuum drying process. Such a modification to the process only involves routine experimentation. In addition, Ogawa et al. teaches a depressurization step (vacuum drying step) after autoclaving and as such this is evidence that the system is capable of repeating a plurality of depressurization processes if required.

Regarding claim 3, Ogawa et al. disclose medical equipment (endoscope) that includes an armor member (sheath) designed to shut out the inside of the medical equipment (endoscope) from the outside thereof and made of a material having softness (see paragraph [0024]-[0027], [0032] of the machine translation).

Regarding claim 4, Ogawa et al. disclose an endoscope having a bending section (9) that is formed adjacently to the distal section of an insertion unit (2), which is inserted into an object, so that it can be bent, and an armor member (sheath) used to sheathe the bending section and made of a material having softness (flexible) (see paragraph [0024] of the machine translation).

Regarding claim 5, Ogawa et al. disclose an endoscope having a communication vent (211) formed so that the communication vent (211) can be

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forcibly unblocked after the completion of the second depressurization process (see paragraphs [0050]-[0053], [0060] of the machine translation).

Response to Arguments

6. Applicant's arguments with respect to claims 1-5 have been fully considered but they are not persuasive.

The Applicant argues on page 3 of the remarks filed August 13, 2008 that *“Ogawa neither discloses nor suggests that the second depressurization process includes a plurality of depressurization processes, the pressure of at least one of which being lower than that of any other of the plurality of depressurization processes performed before it.”*

The Examiner respectfully disagrees. First, this limitation is directed to an intended use of the system. As stated previously, Ogawa et al. discloses that the sterilization process includes a second depressurization step following the autoclaving step (see paragraph [0007] of the machine translation). Since Ogawa teaches a depressurization step (vacuum drying step) after autoclaving this shows that the system is capable of repeating a plurality of depressurization processes if desired or required. In addition, it would have been obvious and well within the ordinary level of skill in the art to repeat the depressurization (vacuum drying process) a plurality of times with a lower pressure each time in order to achieve complete drying of the endoscope. Such a modification to the process only involves routine experimentation. Therefore, the system of Ogawa is capable of performing the claimed functional limitations.

The Applicant further argues on page 4 of the remarks filed August 13, 2008 that *"Palmer's also does not disclose or suggest that the second depressurization process includes a plurality of pressurization processes, the pressure of at least one of which being lower than that of any other plurality of depressurization processes performed before it."* The Applicant goes on to further state that *"It appears that the Examiner only cites Palmer's as disclosing a control unit (micro processor 25) that is 'capable' of controlling the vacuum and autoclaving processes recited in claim 1. Thus, Palmer's does not expressly teach the vacuum and autoclaving processes as recited in claim 1."*

Since claim 1 now positively recites a control unit that is configured to carry out the above step, such a feature must be expressly shown in the reference or the claim allowed. That is, a reference merely teaching a controller that is 'capable' of performing the feature is irrelevant when such a feature is positively recited in the claim, as is the controller configuration recited in claim 1."

The Examiner respectfully disagrees. Palmer has been relied upon to simply teach that it is well known to use a controller to control operation of a sterilization process in an autoclave. Ogawa teaches or suggests the claimed process steps but fails to mention the use of a controller. It would have been obvious to utilize a controller of Palmer to carry out the process steps disclosed or suggested by Ogawa et al.

Therefore, claims 1-5 remain rejected under Ogawa et al. in view of Palmer's as stated above.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Conley whose telephone number is 571-272-8414. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 5, 2008

/Sean E Conley/
Primary Examiner, Art Unit 1797